Michigan Department of Health and Human Services
Program Policy Division
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MDHHS
Michigan Department of Health & Human Services
GRETCHEN WHITMER, GOVERNOR | ELIZABETH HERTEL, DIRECTOR

June 24, 2021

<Provider Name>
<Provider Address 1>
<Provider Address 2>
<City> <State> zipcode5-zipcode4

Dear Durable Medical Equipment Provider:

The Michigan Department of Health and Human Services (MDHHS) is issuing this letter in response to durable medical equipment (DME) provider inquiries regarding the June 15, 2021, U.S. Food and Drug Administration's (FDA) announcement of the Philips voluntary recall of specific Bi-Level Positive Airway Pressure (Bi-PAP), Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices. DME providers who supply the products indicated in the recall must follow the instructions provided by Philips. Further, the DME provider must communicate with beneficiaries and their treating practitioners to identify impacted devices and follow the treating practitioner's alternative treatment plan until the device has been repaired or replaced. The FDA recall notice may be accessed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts.

Providers have expressed concern regarding the impact the recall may have on beneficiary compliance required by current Medicaid BI-PAP/CPAP policy. Current policy specifies for consideration of continued need beyond the initial four months coverage period documentation must substantiate beneficiary compliance in wearing the BI-PAP or CPAP. To be considered for continued coverage the compliance documentation must be submitted with the prior authorization (PA) request. The Philips recall indicated beneficiaries using any of the recalled BI-PAPs/CPAPs should discontinue wearing the device and contact their treating practitioner to consider other treatment options. The manufacturer further stated if no other alternative treatment is available, the treating practitioner should be consulted to assess if the treatment value of continued use of the device outweighs the potential health risks listed in the recall. It is unknown as to the number of impacted Medicaid beneficiaries or when the impacted devices will be repaired or replaced. DME providers must continue to maintain device use logs to record beneficiary compliance.

The following recall information must be documented in the beneficiary file and submitted with PA requests for continued coverage:

- Recall date.
- Recalled device brand/model/serial number.
- Dates the beneficiary did not use the device while waiting for repair or replacement.
- Brand/Model/Serial Number of replacement device or part numbers (if repair).
- Actions taken to repair/replace the device (e.g., provider, manufacturer, beneficiary communications).
- Date of repair (include service ticket) or date replacement device was delivered to the beneficiary (include delivery slip).

The recall notice instructed ventilator patients not to alter their ventilator therapy or discontinue use of their ventilators until they have contacted their treating practitioner for further guidance. The recall documentation for ventilators is the same as above and must be kept in the beneficiary file. Providers must submit this documentation with PA requests for continued coverage. Refer to the Medical Supplier Chapter in the MDHHS Medicaid Provider Manual for BI-PAP, CPAP and Ventilator standards of coverage, other documentation, and PA requirements. The MDHHS Medicaid Provider Manual is located at www.michigan.gov/medicaidproviders >> Policy, Letters & Forms >> Medicaid Provider Manual.

An electronic version of this document is available at www.michigan.gov/medicaidproviders >> Policy, Letters & Forms.

Sincerely,

Kate Massey, Director
Medical Services Administration